

08/982,965



## UNITED STATES DEPARTMENT OF COMMERCE

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/982,965	12/02/97	LOWELL	G 359292000110
			EXAMINER

HM12/0327

JOHN F MORAN  
OFFICE OF COMMAND JUDGE ADVOCATE  
HQ USAMRDC DEPT OF THE ARMY  
FORT DETRICK  
FREDERICK MD 21702-5012

BUREAU OF PATENTS	PAPER NUMBER
	18

1648

DATE MAILED:

03/27/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

## OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 1/5/01

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

- ☒ Claim(s) 1-4, 6-9 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☐ Claim(s) \_\_\_\_\_ is/are allowed.  
☒ Claim(s) 1-4, 6-9 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☒ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

BEST AVAILABLE COPY

The status of the related application(s) cited at the first page of the specification should be updated, if necessary, to ensure a properly completed file record.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The Examiner acknowledges Applicant's Amendment, Paper No. 17, filed January 5, 2001. In view of Applicant's Amendment, the status of the claims is as follows: Claim 5 has been canceled; Claims 1-4 and 6-9 are currently pending before the Examiner.

The oath or declaration remains defective. A new oath or declaration in compliance with 37 C.F.R. 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. 602.1 and 602.02. The oath or declaration is defective because:

- (1). It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. § 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose material information as defined in 37 C.F.R. 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.
- (2). Applicant has not given a post office address anywhere in the application papers as required by 37 C.F.R. 1.33(a). A statement over Applicant's signature providing a complete post office address is required. Further, Applicant's residence address is illegible.
- (3). The continuation data as presently amended at the first line of the specification is not consistent with any claims for priority set forth in the Oath and Declaration. Applicant should submit a new oath properly claiming priority to the appropriate parent applications.

Further, Applicant is **required** to request a corrected filing receipt setting forth the continuation data and the relationship of the parent applications to the instant application to properly complete the file wrapper.

5           It is noted that Applicant has indicated that a new Oath and a Request for Corrected Filing Receipt will be filed (see Paper No. 17, page 3). However, no such papers are currently found in the file record. Applicant is should file the proper Oath and Request for Corrected Filing Receipt in response to this Office Action.

10           The rejection of claims 1-4 and 6-9 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is  
15           withdrawn in view of Applicant's arguments with respect to the data set forth in Table 6.

          Claims 1-4 and 6-9 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant  
20           regards as the invention. Claim 1 is vague and indefinite in the recitation "which may range from 1:1 and 1:20" since the language "may" renders the claim open ended and indefinite since it is unclear at what ratios the complex will be formed. Amendment of claim 1 to recite "are present in a ratio of from 1:1 to 1:20"  
25           would obviate this rejection.

          Upon review of Applicant's parent application, 07/065,440, Applicant **IS NOT** accorded benefit of the filing date of the earlier filed application. The specification of application Serial No. 07/065,440 does not provide support for gp160-proteosome complexes  
30           as presently claimed.

Claims 1-4 and 6-9 remain rejected under 35 U.S.C. § 103 as being unpatentable over Lowell et al. (U) or Lowell et al. (V) or Smith et al. (W) or Avraham et al. (X) in view of Ratner et al. (Y) for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant reiterates previous arguments that the rejection constitutes an "obvious to try" argument (see Paper No. 17, page 4, fourth full paragraph) and further argues that the high degree of unpredictability in the vaccine arts weighs against the obviousness of the claimed invention (see Paper No. 17, last paragraph). This is not persuasive.

As stated in the last Office Action, Applicant's claims are only directed to compositions and methods for inducing antibodies, not vaccine for preventing HIV infection. As gp160 is a large protein and since proteosomes were known in the art to enhance immunogenicity, one of ordinary skill in the art would have reasonably concluded that a composition of gp160 and proteosomes would reasonably give rise to antibodies specific for gp160. Further, Lowell et al. (U) teach that "the proteosome system has potential as an important vehicle to enhance the immunogenicity of peptide vaccines in general" (see page 802, column 2, last sentence, emphasis added). Lowell et al. (V) teach "Since proteosomes have been safely given to many people and since important antigenic determinants are generally hydrophilic, this system should be widely applicable to the development of peptide vaccines for human use" (see page 662, first full paragraph, emphasis added). Thus, Applicant's own prior work teach the broad application of proteosomes to vaccine production. Therefore, the prior art provides a reasonable expectation of success and does not constitute an "obvious to try" argument. The rejection is deemed proper and is maintained.

With respect to the issue of unpredictability of the vaccine arts, the Examiner agrees that development of effective vaccines is highly unpredictable. However, Applicant is arguing limitations not found in the claimed invention. As stated above, the claimed invention is only directed to compositions capable of eliciting antibodies. There is no requirement in the claims for a vaccine or for a protective immune response to HIV, a necessary caveat for a vaccine. Were the claimed subject matter directed to vaccines, issues of enablement for a vaccine for HIV would arise. This is not the case here. The claimed invention is a composition, not a vaccine. As such, the only requirement of the claimed invention is that the composition cause the production of antibodies to gp160. One of ordinary skill in the art would have a reasonable expectation of success in producing the claimed compositions because gp160 is a large molecule (MW=160kD) and it was well known in the art at the time the claimed invention was made that viral envelope proteins were immunogenic and, indeed, were a primary target for vaccine development. Thus, as stated in the preceding paragraph, one of ordinary skill in the art at the time the claimed invention was made would have been motivated to produce the claimed compositions and would have had a reasonable expectation of success in producing the compositions and using them to elicit antibody responses to HIV gp160.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

**A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE**

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ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

5 Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

10 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James  
15 Housel, can be reached at (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.



Robert D. Budens  
Primary Examiner  
Art Unit 1648

20 rdb  
March 23, 2001